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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,232	07/09/2003	Babak B. Roshdieh	HM-88223	2332

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/617,232	Applicant(s) ROSHDIEH ET AL.	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. It is noted that applicant claimed the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) was included in the first sentence(s) of the specification following the title or in an application data sheet. The reference included the relationship of continuation-in-part of the parent application 10/371,277 filed on 02/20/2003.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

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The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

4. The abstract of the disclosure is objected to because of legalese. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: use of legalese in specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by McEvoy (3515128). McEvoy discloses a skin biopsy device 10 having a handle 18 connected to a cutting edge 16 wherein said cutting edge is part of a disposable tip member (column 2, line 65 and Figure 2) that is releasably connected 42 to said handle and is constructed of metal. For claim 2, McEvoy shows in Figure 5 that the disposable tip member is releasably connected to handle by a friction joint (column 1 line 63). For

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claim 3, McEvoy discloses a disposable tip member 12 having a base 46 and cutter walls 16 that have a bottom end connected to said base that extend to the cutting edge. For claim 4, McEvoy shows that the bottom end is embedded into the base. For claim 5, McEvoy discloses a bottom end connected to an outwardly extending flange 68. For claim 6, McEvoy shows in Figure 5 that the disposable tip member includes a cap structure 66 overlying the base and portion of sidewalls. For claim 7, McEvoy discloses a disposable blade attached by joint means (column 1 line 63).

8. Claims 8-11, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins (6155989). Collins discloses a skin biopsy device comprising a handle 2 having a center passage 5 and a discharge end, a plunger 4 positioned within center passage having an actuating end and a contact end, and a releasably attached tip member 3 including a biopsy chamber 6 having an outermost open end defined by a metal cutting edge, where said biopsy chamber includes a push rod 8 having a disc end in communication with said open end and plunger. For claim 9, Collins shows a movable plunger and integral push rod in Figure 1 where the center passage includes a biasing means for maintaining the plunger in its first position (column 2 line 42). For claim 10, Collins shows a tip member having a base and a biopsy chamber defined by the cutter walls 3 extending from cutting edge to a bottom end which is connected to the base. For claim 11 and 17, Collins discloses cutter walls constructed of metal (column 2 line 47). For claim 13, Collins shows the bottom end embedded in said base in Figure 1.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins as applied to claims 8-11 and 13 above, and further in view of Allen (5341816). Collins discloses the claimed invention except for the disposable serrated cutting edge. Allen teaches a serrated cutting edge 42 used in a biopsy device as seen in Figure 3A of Allen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Collins, with Allen since it was known in the art that a serrated cutting edge is used to provide an increase in cutting efficiency owing to a plurality of cutting surfaces as opposed to a singular one.

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins as applied to claims 8-11 and 13 above, and further in view of McEvoy. Collins discloses the claimed invention except for the fastening means between bottom end of disposable tip member and its base. McEvoy teaches using a fastening means for connecting a disposable biopsy tip member 42 to the biopsy handle and plunger. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Collins, with McEvoy since it was known in the art that a fastening means is used to provide a disposable tip member.

13. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins as applied to claims 8-11 and 13 above, and further in view of McEvoy. Collins discloses the claimed invention except for the bottom end including a cap structure overlying base and included on the disposable tip member's bottom end. McEvoy teaches a cap structure 66 overlying the base and disposable tip member that protects the disposable tip from contamination. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Collins, with McEvoy since it was known in the art that the fitting of end caps protects against damage and soiling (McEvoy, column 2 line 67).

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins as applied to claims 8-11 and 13 above, and further in view of McEvoy. Collins discloses the claimed invention except for the tip member and cutting edge connected by a joint means. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Collins, with

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McEvoy since it was known in the art that fastening via joint means provides a means for a disposable cutaneous biopsy device to obtain a specimen.

15. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Collins as applied to claims 8-11 and 13 above, and further in view of McEvoy. Collins discloses the claimed invention except for the tip member and cutting edge connected by a joint means. McEvoy teaches a threaded portion 42 that is detachably secured to the body assembly. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the biopsy device as taught by Collins, with McEvoy since it was known in the art that fastening via any joint means relying on frictionally releasable members provides a means for a disposable cutaneous biopsy device to obtain a specimen and be released.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yuan et al (5833628) teaches a biopsy device with a handle, plunger and disposable tip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

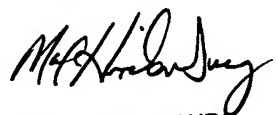
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JGH



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